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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,010	06/26/2003	Ed Austin	39262/285776	4956

30559 7590 06/22/2007

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EXAMINER	
SHAFFER, RICHARD R	
ART UNIT	**PAPER NUMBER**
3733	

MAIL DATE	DELIVERY MODE
06/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/607,010	AUSTIN ET AL.	
	Examiner	Art Unit	
	Richard R. Shaffer	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,17-21,23-25,28-34,36 and 41-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,17-21,23-25,28-34,36 and 41-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 17, 30-34, 36 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faccioli et al (PCT Publication WO 00/40163) in view of Lee et al (US Patent 5,405,347).

Faccioli et al disclose an external fixation apparatus comprising: a first member (**3**) attachable to the tibia (**Figure 2B**) by pins (**5**); a pivot arm (**20** and **35** together) having a first and second end; the pivot arm coupled to the first member through a lockable (at least when the system is fixed) ball joint (top of **2**, bottom of **3**, **Figure 2B** or the ball joint between **20** and **2**); an asymmetric pin clamp (**40, 50**) rotatable about **[First Interpretation of element 35:** a push/pull pin (**35**)**] [Second Interpretation of element 35:** the second end of pivot arm/shaft extending transversely therefrom**]**; the pin clamp having first (**40**) and second (**50**) jaws; a hole (**38**) within the first jaw (**4**) that receives shaft (**35**); bolts (**43, 59**) pass through openings in the first and second jaws to bias/tighten the clamps together; and the pin clamp is attachable to a talus or calcaneus.

Faccioli et al disclose all of the claimed limitations except for carriage having two threaded holes receiving a worm gear and keybolts that operate each worm gear in

order to allow to allow lateral movement along two axes. Lee et al teach (**Figures 1-11; Column 1, Line 15-55)** that prior art devices attempted to accommodate for the occurrence when a surgeon realizes a section of fractured bone is out of alignment and is thus required to correct the fixation system by pivotally linked fixator rods. Lee et al did not disregard the pivotal movement, but stated that lateral movement was an important motion to allow a surgeon to realign the fixation device without removing bone pins. Lee et al used a worm gear (elements 46, 30 and 52) to provide for lateral movement. It would have been obvious to one having ordinary skill in the art to provide for lateral motion through the use of a worm gear in order to better assist a surgeon in realignment of the fixation device thereby avoiding bone pin removal and re-insertion.

Lee et al however taught that the worm gear was rotatable and thus capable of an infinite amount of axes and therefore did not disclose the use of a second worm gear. It has been held that mere duplication of the essential working parts of a device involves only routine skill in the art, see *St. Regis Paper Co v Bemis Co.*, 193 USPQ 8. This is deemed relevant since applicant's invention merely serves a lesser function (two axes versus infinite) to which *In re Karlson*, 136 USPQ 184 states that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. Applicant wished to have two axes instead of infinite. It would have been obvious to one having ordinary skill in the art to provide two worm gears should only two axes be desired for lateral motion by removing the rotatable motion along the longitudinal axis of the device.

Further, one having ordinary skill in the art would have provided the worm gears to the device of Faccioli et al in order to maintain all previous functionality (i.e. telescoping motion) and therefore would have reasonably concluded such device would be appropriate in the components of elements (**3** and **20**).

In regard to claim 32, such a method step is deemed a matter of obvious design choice to one having ordinary skill in the art at the time of invention because a surgeon would clearly have his/her own preference whether the first member or pin clamp is fixed first as well as applicant having no criticality for such a method step. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Claims 25 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pennig (US Patent 5,827,282).

Pennig discloses a system (**Figures 1-9**) comprising: a first member (**22**, shown in **Figure 3**); a second member/pivot arm (**11, Figure 1**) having a shaft (**6**) with a circumferential groove (**15**); a pin clamp (**1, Figure 1**); the pin clamp having a first jaw (**3**) and a second jaw (**2**); a hole is located in the first jaw to receive the shaft (**6**); bolts (**4**) are received in order to bias the two jaws together; a locator pin (**16**) is received within the groove to hold it into place; and the locator pin can be pushed or pulled to allow release of the shaft.

Pennig discloses all of the claimed limitations except for a snap-fit connection between located pin (**16**) and groove (**15**). It is well known in the art that by providing a snap-fit connection, the user is given an audible as well as tactile response signifying a connection has been made. This is especially important during surgical procedures

where any error can have a detrimental effect. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide for a snap-fit connection between the pin (**16**) and groove (**15**) to provide a surgeon a simple means for confirming a stable connection between the two components has been made.

Claims 18, 19, 20, 21, 23 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pennig (US Patent 5,827,282) in view of Lee et al.

Pennig discloses all of the claimed limitations except for the second member having two portions that translate relative to one another through the use of a carriage containing two worm gears with keybolts as well as a bolt being received through the first and second jaws such that it interferes with the shaft and locks rotation of the pin clamp about the pivot arm.

As described previously, Lee et al teaches the use of a worm gear for lateral movement. It would have been obvious to one having ordinary skill in the art at the time of invention to provide two worm gears to the device of Pennig in the portion corresponding to element (**7**) for the reasons listed previously.

Further, it would have been a matter of design choice to have bolt (**17**) pass through the first and second jaws (instead of just the first jaw) by allowing the second jaw (**2**) to have an extended portion to also receive element (**17**) since applicant has not stated any criticality for the bolt to pass through two jaw members instead of merely one. The end result is the same; the bolt interferes with the shaft and locks rotation of the device. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Claims 24, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pennig in view of Lee et al and in further view of Hoffman et al (US Patent Application 2002/0077629).

Pennig in view of Lee et al disclose all of the claimed limitations except for biasing elements that receive bolts (**4**) and are capable of biasing both jaws together. Hoffman et al teach (**Page 3, Paragraph 0028**) that coil springs (**10 and 10'**) holds the plates partially apart (loose connection) in order to ease installation of the bone pins in-between the jaws. Further, the springs would bias the jaws in alignment by being placed within their cavities and inherently would bias them slightly together (if pulled beyond their equilibrium point or if stretched and tied around the jaws). It would have been obvious to one having ordinary skill in the art at the time of invention to provide coil springs as taught by Hoffman et al to the device of Pennig in view of Lee et al in order to make it easier for the surgeon to install the bone pins within the pin clamp.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Richard Shaffer
June 17th, 2007

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER